NIH POLICY MANUAL

4120 - GRANT APPEALS PROCEDURE Issuing Office: OER 301-496-5358

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A. Purpose:

This issuance describes the NIH procedure for resolving certain post-award disputes between grantee institutions and the NIH.

The NIH grant appeals procedure provides NIH the opportunity to review decisions of its officials and to settle certain disputes with grantees, and fulfills the requirement for a preliminary appeals process before an appeal may be submitted to the Departmental Appeals Board for resolution.

B. Applicability:

This policy is applicable to all NIH assistance awards, i.e. grants and cooperative agreements, but not contracts or joint endeavors or interagency agreements. Hereinafter assistance awards will be referred to as "grants," and awardee institutions as "grantees."

C. References:

- 1. Code of Federal Regulations, Title 45, Part 16, Procedures of the Departmental Appeals Board.
- 2. Code of Federal Regulations, Title 42, Part 50, Subpart D, Public Health Service Grant Appeals Procedure.
- 3. PHS Grants Administration Manual, Part 137, Grant Appeals Procedures.
- 4. NIH Manual Chapter <u>1743</u>, Keeping and Destroying Records.

D. Background:

The Secretary of Health and Human Services has established a Departmental Appeals Board for the purpose of reviewing and providing hearings upon post-award disputes which may arise in the administration of HHS grants. The regulation (45 CFR Part 16) that establishes the Board authorizes HHS agencies to establish informal appeals procedures which must be exhausted before a formal appeal to the Departmental Board

will be allowed. The PHS procedure is published as a regulation at 42 CFR, Part 50, Subpart D. This chapter implements the PHS procedure with respect to NIH grant programs.

E. Policy:

The NIH grant appeals procedure must be used, where applicable, in the resolution of post-award disputes (see section F. below) between grantees and NIH awarding Institutes, Divisions, and Centers (awarding organizations). When these disputes are not resolved to the grantee's satisfaction under this procedure, th grantee then may, within specified limits with regard to time and scope, appeal to the Departmental Appeals Board established under 45 CFR Part 16.

F. Scope:

- 1. Grantees may appeal directly to NIH the following post-award adverse determinations made in writing by NIH officials:
 - a. Termination, in whole or in part, of a grant for failure of the grantee to carry out its approved project in accordance with the applicable law and the terms and conditions of such assistance, or for failure of the grantee otherwise to comply with any law, regulation, assurance, term, or condition applicable to the grant.
 - b. A determination that an expenditure not allowable under the grant has been charged to the grant or that the grantee has otherwise failed to discharge its obligation to account for grant funds.
 - c. A determination that a grant is void. "Void" means a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained.
 - d. A denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.
- 2. a. Grantees may appeal directly to NIH indirect cost rate determinations made by the Financial Advisory Services Branch, Division of Contracts and Grants, affecting current or new commercial grantees.
 - b. Grantees may appeal directly to the affected DHHS Regional Director (or to another regional Departmental official designated by the Director) pre-award or post-award determinations made by DHHS Regional Divisions of Cost Allocation on the establishment of indirect costs rates, research patient care rates, fringe benefits, or other negotiated rates. Details concerning the procedures to be followed in filing such an appeal are contained in Code of Federal Regulations, Title 45, Part 75, Subpart A, Indirect Cost Appeals.

G. Responsibilities:

- 1. The Director, NIH designates the Deputy Director for Extramural Research (DDER) to oversee the administration of the NIH grant appeals procedure.
- 2. The DDER appoints the NIH Appeals Officer, who is responsible for administering the NIH grant appeals procedure, permanently chairing the NIH Grant Appeals Board, and managing the review of individual appeals.

H. NIH Grant Appeals Board:

NIH Grant Appeals Board All eligible post-award appeals will be reviewed by a review committee, called the NIH Grant Appeals Board (Board). The following describes the Board's structure, function, and operating procedures:

- 1. The Board consists of a minimum of three members. The individuals on the Board must be in positions commensurate with the responsibilities of the Board.
- 2. The DDER appoints the Chairperson for an indefinite or specified (at least one year) term. The DDER also designates an alternate Chairperson in those instances where the permanent Chairperson may be disqualified as a result of the nature of the appeal.
- 3. The members may be appointed by DDER to serve on a standing basis, by the Chairperson on a one-time basis, or by a combination of both methods.
- 4. None of the Board members reviewing an appeal may be from the organization whose adverse determination is being appealed or who have previously acted in the matter, or who are subject to line supervision under an official who acted in the matter, or otherwise had an actual or apparent conflict of interest regarding the case under appeal.
- 5. While reviewing an appeal, the Board may grant an extension of time for presenting a case for good reasons; dismiss a case for failure to meet deadlines or other requirements; remand a case for further action by the affected organization; close or suspend a case that is not ready for review; request relevant information from the responsible parties; or waive or modify these procedures in a specific case with written notice to the involved parties.
- 6. The function of the Board is to make an independent evaluation of the facts as presented by both the office that made the adverse determination and the grantee. Consequently, the Board shall not consider any information outside the record established for reviewing the appeal. When one of the parties submits information to the Board independently or upon request, this information will be made part of the record and the Board shall make it available to the other party with the opportunity to comment, unless the Board determines that the submission of the additional comments is unnecessary or would serve only to

delay the resolution of the appeal.

- 7. Generally, the Board's review will be restricted to determinations of whether the adverse determination is clearly erroneous in fact or policy, or is arbitrary or unreasonable as measured against NIH's established management practices. However, if the Board finds that the record is inadequate for a particular decision to have been made by the NIH awarding component, the Board may use any other appropriate approach to resolve the issue equitably and expeditiously.
- 8. The decisions of the Board are not precedent-setting and each case must be evaluated on its individual merits, regardless of the similarity with previous situations.
- 9. All decisions of the Board affecting the rights of the parties shall be in writing, with copies to both sides, served by personal service, or certified mail, return receipt requested.

I. Procedures:

- 1. Notice of Adverse Determination
 - a. Adverse determinations by NIH awarding organizations, identified in F.1. a-d. and F.2.a., must set forth the reasons for the determination in sufficient detail to enable the grantee to respond thoroughly and substantively.
- b. The notice of adverse determination must include the following statement:

"This determination may be appealed in writing by the grantee institution in accordance with 42 CFR Part 50, Subpart D, to the NIH Appeals Officer, Room 254, Shannon Building, Bethesda, Maryland 20892. The appeal, requesting a review of the determination, must clearly identify the question in dispute; fully state the grantee's position regarding the question, including the pertinent facts and reasons in support of the position; and enclose a copy of this determination with the appeal. The appeal must be signed by both the institutional official authorized to sign assistance award applications and the principal investigator, and must be postmarked no later than 30 days after the postmarked date of this notice."

2. Submission of Appeal

- a. A grantee institution that requests an NIH review of an adverse determination must submit a written request to the NIH Appeals Officer no later than 30 days after the postmarked date of the written notification of determination. The NIH Appeals Officer, who serves as Chairperson of the NIH Grant Appeals Board, may grant an extension of time for preparing an appeal if good cause is shown.
- b. Although the request for review need not follow any prescribed form, it must contain a full statement of the grantee's position with respect to the disputed

matter and the facts and reasons in support of this position. The grantee must include a copy of the notice of adverse determination with the submission.

c. The NIH Appeals Officer shall transmit a copy of the appeal to the Director, DGC/ORM/OM/PHS.

3. Acceptance of Appeal

- a. Upon receipt of a request for review by the NIH Grant Appeals Board, the Chairperson will determine whether the issue is appealable in accordance with the provisions described in F.1.a-d. or F.2.a., and promptly notify the grantee whether the appeal has been accepted for review.
- b. The Chairperson will promptly send a copy of the notification to the Director and the chief extramural programs officer of the awarding organization, who will promptly inform the grants management officer of the appeal. In the case of appeal of an audit determination or an indirect cost rate determination made by the NIH Financial Advisory Services Branch, the Chairperson will notify the Director, Division of Contracts and Grants, NIH.
- c. When a request for review has been accepted, no further action may be taken by the awarding organization pursuant to the adverse determination until the request has been considered by the Board, except that receipt of a request for review does not affect the authority which the organization may otherwise have to suspend assistance or withhold or defer payments under the grant during the appeals review. In addition, because of additional information received with the appeal or for other valid reasons, the responsible organization may wish to attempt to resolve the dispute through direct informal negotiations with the grantee. If settlement is achieved, the responsible organization staff must contact the Chairperson who, in turn, will arrange to have the settlement entered into the record, with the consent of the parties, as the final disposition of the appeal.

4. Review of Appeal

- a. The NIH Grant Appeal Board will, when possible, complete the review within 45 days.
- b. After acceptance of a request for review, the organization official who made the adverse determination will be requested to provide the Board with copies of all background material and documents serving as the basis for the determination. This material is to include a copy of the determination which is being appealed, the grant application and summary statements, notice of grant award(s), all correspondence between the parties pertinent to the appeal, text of the pertinent policies or regulations, audit data, and any other applicable information.

- c. Both grantee and NIH staff may be invited by the Board to discuss pertinent issues, or to submit additional information deemed necessary. The additional information will be included in the official record. It will be provided to the other party with the opportunity to comment, unless the Board determines that submission of additional comments is unnecessary or would serve only to delay the resolution of the appeal. If a secondary party was involved in the development of the adverse determination, the secondary party will be notified that additional information has been made available.
- d. Based on the Board's review and a majority vote, a written decision will be prepared for the signature of the Chairperson and all members of the Board. Dissenters will sign as dissenting.

5. Notice of Decision

- a. The Chairperson will send the NIH Grant Appeals Board's decision to the grantee by certified mail and to the organization Director and the organization chief extramural programs officer, who will promptly inform the grants management officer, or to the Director, Division of Contracts and Grants, NIH, in the case of audit determinations and indirect cost rate determinations made by NIH. The responsible NIH organization staff will follow-up with appropriate action.
- b. If the decision sustains the grantee's position, the case will be deemed ended for purposes of appeal.
- c. If the decision is adverse to the grantee's position, it must include the following statement concerning the grantee's right to appeal to the Departmental Appeals Board:

"This is the final decision of the National Institutes of Health. It will become the final decision of the Department of Health and Human Services unless you appeal within 30 days after you receive this decision to the Departmental Appeals Board in accordance with the provisions of 45 CFR Part 16. If you decide to appeal, you must mail or deliver your Notice of Appeal (registered or certified mail should be used to establish the date) to the Departmental Appeals Board, Room 2004, Switzer Building 3rd & C Streets, S.W., Washington, D.C. 20201. Your Notice should include a copy of this decision and state the reasons for your disagreement with it. (Please send a copy of your Notice to the NIH Appeals Officer, Room 254, Shannon Building, Bethesda, Maryland 20892.) The Departmental Appeals Board will notify you of further procedures."

d. All proceedings will be appropriately documented and retained in NIH files. Internal procedures must ensure that files are kept and destroyed in accordance with NIH policy (NIH Manual 1743 Keeping and Destroying Records, Appendix 1, Part 3, Section E, Appeals and Litigations). This material will be

available to the Departmental Appeals Board in case of a formal appeal.

J. HHS Appeals Procedure:

- 1. If a formal appeal of an NIH adverse determination is made to the Departmental Appeals Board, the Executive Secretary of that Board will send a copy of the appeal to the Director, Division of Grants and Contracts (DGC), Office of Resource Management (ORM), OASH.
- 2. The DGC will request the Deputy Director for Extramural Research (DDER), NIH, to develop the necessary information and send it directly to the Executive Secretary of the Departmental Board with a copy to DGC.
- 3. The Departmental Appeals Board, upon completion of its deliberations, will send its decision to the grantee and the Director, DGC, OASH. DGC will send appropriate notification to the Director, NIH. This information will be transmitted through DDER to the responsible BID Director for appropriate action. A copy will be sent to the Appeals Office for information.

K. Effective Date:

This policy is effective on date of release.

L. Additional Information:

For more information on this chapter contact the NIH Appeals Office, OER, Shannon Building, Room 254, telephone 496-5358.

M. Additional Copies:

For extra copies of this chapter, submit a Form NIH-414-5 "Request for Manual Chapter," to the Printing and Reproduction Branch, Division of Technical Services, Building 31, Room B4B-N-09.

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